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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,490	01/31/2001	Shengfang Jin	07334-138001	3043

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FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/774,490	JIN, SHENGFANG	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-27,29-38,41-46 and 49-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-27,29-38,41-46 and 49-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 39, 40, 47 and 48 have been canceled. Claims 51-65 have been added. Claims 23, 33 and 34 have been added. Claims 23-27, 29-38, 41-46 and 49-65 are pending and under consideration.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

3. The rejection of claims 23-27, 29-38, 41-46, 49 and 50 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons of record. Claims 51-65 are also rejected for the same reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. .

The claims encompass the gene encoding the protein encoded by SEQ ID NO:1. The specification has identified SEQ ID NO:1 as a polynucleotide which is unregulated in drug resistant EMT-6 cells (Teicher et al, Science, 1990, Vol. 247, pp. 1457-1461, cited in the previous action). The claims are drawn to a gene which encodes the protein encoded by SEQ ID NO:1. It is recognized in the art that a eukaryotic gene includes regulatory regions and non-coding regions (Rieger et al, Glossary of Genetics, 1991, page 190, lines 15-28, cited in the previous action) which affect the level of the expressed polypeptide. The specification has not disclosed the portion of the gene which affects the expression of SEQ ID NO:1 when the cell is in a drug resistant versus drug susceptible state. It is well known in the art that that the description of an expressed polynucleotide is commensurate with a mRNA, and that the sequence of a mRNA provides no information as to the structure of the complete gene involving the sequence of enhancers, promoters and introns, from which the mRNA is processed. The art recognizes that the structure of a gene is empirically determined. for example, the untranslated regulatory and structural elements of a gene mediating the expression of a housekeeping protein or a protein which is tissue specific would be expected to be much different from the structure of the instant gene encoding the protein encoded by the mRNA or cDNA of SEQ ID NO:1. Thus,

the description of an expressed polynucleotide does not fulfill the description of a "gene". One of skill in the art would reasonably conclude that applicant was not in possession of the isolated gene.

Applicant argues that the gene is not being claimed. This is not persuasive. When given broadest reasonable interpretation, the claims require the full gene expressing SEQ ID NO:1. If a method dependent upon a product which lacks adequate written description, the method itself lacks adequate written description. Applicant argues that the reference to the "gene" is just a convenience for identifying the polynucleotide that is being measured. This is not persuasive. It is clear that the candidate modulator of drug resistance would affect the level of expression of the polynucleotide that is being measured by interfering with transcription or translation of the mRNA encoded by the polynucleotide (gene). In the case of interfering with the transcription of the mRNA the candidate agent is interacting with the regulatory region of the gene. Thus, when given the broadest reasonable interpretation of the method claims as they pertain to the modulation of drug resistance by the candidate agent which affect the transcription of the gene by means of interfering with the regulatory region(s) of the gene, an written description of the gene is required.

4. Claims 23-25, 27, 29-36, 38, 41-46, 49 and 50-65 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods using a cell which expresses SEQ ID NO:1 from an endogenous gene, does not reasonably provide enablement for methods using a cell which expresses SEQ ID NO:1 from an expression vector. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims..

The instant claims are drawn to a method of screening of candidate modulators of a gene encoding a polypeptide comprising an amino acid sequence encoded by SEQ ID NO:1 in a eukaryotic cell b

It is well recognized in the art that expression of eukaryotic genes is regulated by transcription and/or translation. In the case of transcriptional regulation, the transcription of the mRNA is governed by regulatory regions located within the non-expressed portion of the genome, and which include regions within the promoter, the introns and enhancer regions which

are not necessarily proximate to the expressed gene (Rieger et al, Glossary of Genetics, 1991, page 190, lines 15-28, page 479, last line to page 480, line 12, cited in the previous Office action). The specification has provided the sequence of the polynucleotide of SEQ ID NO:1. The claims encompass other polynucleotide which encode the protein encoded by SEQ ID NO:1 and therefore include degenerate coding sequences of SEQ ID NO:1. It is reasonably concluded that if the expression of SEQ ID NO:1 were under the control of a promoter commonly used in recombinant expression in eukaryotic cells, such as the CMV promoter, that said expression would be invariant, because the promoter would not respond to the presence or absence of drugs within the cell. The specification has not disclosed the regulatory regions which control the expression of SEQ D NO:1, and thus, one of skill in the art would be subject to undue experimentation in order to locate and isolate the regulatory sequences controlling the expression of SEQ ID NO:1 within the genomic DNA of the EMT-6-tumor derived cells in order be able to recombinantly express SEQ ID NO:1 under control of the critical regulatory regions necessary for the down regulation or up regulation of SEQ ID NO:1. It is concluded that the specification is not enabling for the to practice the claimed invention in a cell which is not an EMT-6 derived cell.

Applicant argues that the claims are enabled because on of skill in the art would know how to isolate genomic DNA and the corresponding cDNA. This is not persuasive, as the claims encompass the screening of candidate agents which affect transcription of SEQ ID NO:1 as well as translation. The cDNA would not contain the transcriptional control regions.

Applicant argues that it cannot be understood why the examiner is holding enablement only for EMT-6 cells because EMT-6 cells are not the only cells that express SEQ ID NO:1. However, , the examiner is not holding the enablement to EMT-6 cells but to cell comprising an endogenous gene encoding SEQ ID NO:1. It would be reasonably to conclude that the promoter or other regulatory regions which control the expression of SEQ ID NO:1 in cells expressing SEQ ID NO:1 would be affected by candidate test agents which would modulate the level of expression of SEQ ID NO:1 in the cells by means of modulating transcription of mRNA from the endogenous gene.

5. All other rejections and objections as set forth in the previous Office action are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
70/4/2004

KAREN A. CANELLA PH.D
PRIMARY EXAMINER